Erythrocyte-bound apolipoprotein B in diabetes mellitus

Published: 26-10-2016
Last updated: 14-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON43369

Source
ToetsingOnline

Brief title
EBADia

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
artherosclerosis, Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Stichting SFG Interne Specialismen

Intervention

Keyword: Apolipoprotein B, Cardiovascular disease, Diabetes Mellitus

Outcome measures

Primary outcome

The main endpoint of this study will be the value of erythrocyte-bound apolipoprotein B in patients with diabetes mellitus type 1 or 2.

Secondary outcome

Secondary endpoints will be the relation of erythrocyte-bound apolipoprotein B levels in patients with diabetes mellitus type 1 or 2 in association to clinical or subclinical atherosclerosis. Furthermore we will compare the level of and erythrocyte-bound apolipoprotein B in patients with diabetes mellitus against these levels in controls without diabetes mellitus. Finally, we want to study the levels of factors associated with complement activation in relation to ery- apo B values including DNA polymorphism.

Study description

Background summary

Cardiovascular disease (CVD) is a major global health burden and, to date, still the number one cause of death globally [1]. The majority of CVD is caused by atherosclerosis, which is the result of a combination of lipid accumulation and a chronic inflammatory situation resulting in the formation of arterial plaques [2,3].
Lipids play a key role in atherogenesis, the first step being the invasion of the vessel wall by lipid particles [4]. Lipids are transported within lipoproteins. All atherogenic lipoproteins carry apolipoprotein B (apo B) as their structural protein [5]. Increased concentrations of apo B are associated with CVD [6-8]. These apolipoproteins have become standard clinical laboratory measurements. It has been shown previously that apo B can also bind to blood cells such as leukocytes and erythrocytes [9,10].

Recently, our group found evidence that erythrocyte-bound apo B (ery-apo B) is inversely associated with CVD, and that it is unrelated from serum levels of apo B [11]. These studies were performed in patients with and without a history of CVD. Data in other specific groups of patients are lacking.
It remains unclear which determinants are involved in ery-apo B levels in individual patients. We postulated previously that the transport of lipoproteins by ery-apo B is due to binding of apo B containing lipoproteins with complement receptor 1 (CR1) on erythrocytes after complement activation on the surface of these lipoproteins [12]. Around 30% of the variation in ery-apo B can be explained by blood group type O and CR1 expression polymorphism [11,13], but other factors are still unclear.

Diabetes mellitus type 1 and type 2 are strongly associated with atherosclerosis, in the case of type T2DM patients have a two-fold increased risk of cardiovascular disease, patients with T1DM have an 2-4 fold increased risk of cardiovascular disease [14]. Many studies have shown that chronic inflammation is closely linked to atherosclerosis [15-17], and the increased risk in patients with diabetes is due to this chronic inflammation [18,19]. The development of cardiovascular disease within patients with DM differs greatly, one explanation for this difference in cardiovascular risk might the level of ery-apo B.

Study objective

In this exploratory study we aim to explore the values of apolipoprotein B bound to erythrocytes in patients with diabetes mellitus type 1 or 2, to evaluate the relationship with clinical and subclinical atherosclerosis and to compare these results with controls without diabetes.
Furthermore, we want to investigate if there are other factors associated with the levels of blood cell bound apo B, especially factors associated with complement activation.

Study design

The study will be a cross-sectional study.

Study burden and risks

No intervention will take place. Volunteers will visit the outpatient clinic one or two times (depending on availability of a recent IMT measurement). A maximum of 30ml (depending on availability of recent blood results) blood will be drawn. Besides a risk of a hematoma, no other risks are foreseen. Volunteers receive 10 euros for participation. Furthermore, volunteers will be told and given advice if they turn out to suffer from an increased cardiovascular risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group with patients with T1DM or T2DM
- Age of 18 years of older
- Diabetes mellitus type 1 or type 2
Group with controles without T1DM or T2DM
- Age of 18 years of older

Exclusion criteria

Group with patients with T1DM or T2DM
- Use of anti-inflammatory medication
Group with controles without T1DM or T2DM

- Diabetes mellitus type 1 or 2
- Use of anti-inflammatory medication
- Chronic inflammatory disease (e.g. rheumatoid artheritis, inflammatory bowel disease, systemic lupus erythematosus)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2016
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57990.101.16

Study results

Date completed: 05-10-2018

Actual enrolment: 133